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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/664,582 | 09/17/2003 | Stephen C. Rowe | F0397.70070US00 | 3674 |

7590 08/11/2004
Timothy J. Oyer, Ph.D.
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210

EXAMINER

AZPURU, CARLOS A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1615

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/664,582 | Applicant(s) ROWE ET AL. | |
| | Examiner Carlos A. Azpuru | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 18, 19, 21, 29-31, 38, 43, 44 and 46-48 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 10-17, 22-28, 32-37, 39-42, 45, 49 and 50 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/06/08</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt is acknowledged of the information disclosure statement filed 12/02/2003. A preliminary amendment was filed on 03/12/2004.

The claims of copending 10/215,390 were unavailable for review at the time of this examination. Applicant is requested to furnish a copy of these claims in order to review possible double patenting issues.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-6 indefinite in that they fail to fully set out the "predetermined volume" of the photopolymerizable material. It is suggested that applicants set out the purpose of this "predetermined volume" in terms of functional language (therapeutic purpose) in order to particularly point out what is encompassed by the term.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164

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USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 9, 18, 19, and 21 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-16 of U.S. Patent No. 6,468,520 (US'520). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'520 claims a method for treating a targeted region comprising applying an initially fluent prepolymeric material to mammalian tissue, applying a second material to the first in order to chemically initiate polymerization to a polymeric non-fluent material. At least a portion of the targeted region is covered (see claim 14 of US'520). Polymerization occurs due to the reaction of one or more reactive groups selected from acrylates, diacrylates, oligoacrylates, methacrylates, ddimethacrylates, oligomethacrylates, isocyanates, isothiocyanates and amines (see claim 15 of US'520). Both materials are sprayed onto said mammalian tissue (see claim 16 of US'520). Those of ordinary skill would have therefore expected similar therapeutic results from the instantly claimed method given the claims of US'520 given that both claim chemically reactive prepolymeric materials for use in tissue coatings or filling. The instant claims would have been obvious to the ordinary practitioner given the claims of US'520.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-31, 38, 43,44, 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Jishi-Shika Kougyou K.K.

Jishi-Shika Kougyou K.K. disclose an apparatus having an applicator which has a proximal and distal end, the distal end having a fluent emission element constructed and arranged to emit a mixture of a gas and a prepolymeric material from a source of pressurized gas and a source of prepolymeric material (see Drawings). The apparatus has a nozzle for dispersing said prepolymeric material in a spray by mechanical or automatic means (see pump in drawing). The device has a grippable member and a shaft extending from this grippable member. Part of the shaft is non-rigid. The apparatus is used to apply photopolymerizable materials to mammalian tissues. The instant claims are anticipated by Jishi-Shika Kougyou K.K.

Claims 7, 8, 10-17, 22-28, 32-37, 39-42, 45, 49, and 50 are objected to as dependent upon a rejected base claim.

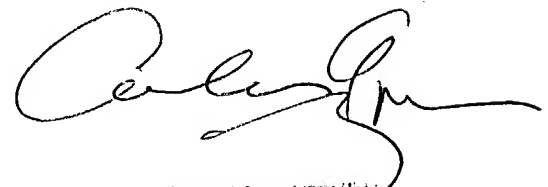
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER
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